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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,049	01/22/2004	Harriet L. Robinson	07917-217002	3662

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,049	ROBINSON ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *8-10,14,15,17-31 and 39-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11-13,16,32-38,42,43 and 52-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/04; 7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges the election, without traverse, of Species 1, Influenza Virus Antigen source and Species "d", Intradermal Administration route directed to a method DNA vaccination, in the reply filed on 1 September 2006. Upon further consideration, the examiner has decided to rejoin all claims.

Claim Status

Claims 1-56 are pending. Claims 1-56 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The oath or declaration, having the signatures of all inventors, received on 10 June 2004 is in compliance with 37 CFR 1.63.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 22 January 2004 and 6 July 2004 consisting of 5 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit from as a CON of 08/187,879 filed on 01/27/1994 (US-PAT 6,841,381), which is a CIP of 08/009,833 filed on 01/27/1993 (US-PAT 5,643,578), which is a CIP of 07/855,562 filed 03/23/1992 (ABN). The instant application has been granted the benefit date, 23 March 1992, from the application 07/855,562. However, the parent, US-PAT 5,643,578, does not have benefit of (1) retroviral promoter, (2) SIV antigen, (3) rotavirus antigen, (4) microsphere encapsulation of DNA, (5) methods of immunization comprising combinations of influenza antigens. Therefore these limitations will be given the benefit of US-PAT 6,841,381, filed on 27 January 1994.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

SCOPE OF ENABLEMENT for PLASMID VECTORS

Claims 1-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an a method of DNA vaccination against infectious agents using a plasmid vector for administration of transcription unit(s) encoding desired antigen(s), does not reasonably provide enablement for similar methods that use viral vectors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Nature of the Invention

The full scope of the claimed invention encompasses DNA vaccines encoding influenza virus antigens, HIV antigens, SIV antigens, and rotavirus antigens that are encoded on plasmid vectors.

Working Examples and Guidance Provided

While the breadth of the presently pending claims encompasses DNA vaccines that can be encoded by vectors other than plasmids. The "DNA transcription unit" as claimed in Claim 1 is not limited to plasmids. However, the working examples of the instant application only demonstrate the use of plasmid expression systems. Despite the fact that the claims can be broadly interpreted to include viral expression vectors, the instant specification and drawings only give guidance for plasmid systems.

State of the Art and Analysis of the Issues

DNA vaccines encoded in and administered by adenoviruses were available at the time of the instant invention, as taught by Morin et al. 84 (13): 4626. (1987). Nevertheless, the application does not make mention of this alternative form of delivery for antigen genes. If one were to try to apply the claimed invention in a viral vector expression system, additional experimentation would be required.

Specifically, Morin et al. indicate the difficulty in developing animal models, using adenoviral vectors for vaccination. "Human adenoviruses have a highly restricted host

range, which makes development of a useful animal model for adenoviral disease difficult." (page 4630). Furthermore, Morin et al. describe induction of humoral immune responses that were not specific against the antigen of interest, Hepatits B Surface antigen, "[s]ome animals receiving high doses of adenovirus recombinants mounted a humoral immune response to adenovirus antigens but not to HBsAg." (page 4630).

Therefore, the quantity of experimentation required to make and use the invention, as claimed, is insufficient to enable scope of the invention as a method of DNA vaccination through administration of a viral vector expression system.

SCOPE OF ENABLEMENT for ROUTE OF ADMINISTRATION

Claims 1-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some methods of DNA vaccination using intravenous, intramuscular, intraperitoneal, intradermal and subcutaneous routes of administration, does not reasonably provide enablement for all routes of administration (intravenous, intramuscular, intraperitoneal, intradermal and subcutaneous). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Nature of the Invention

The full scope of the claimed invention encompasses DNA vaccines delivered by various routes of administration (intravenous, intramuscular, intraperitoneal, intradermal

and subcutaneous) encoding influenza virus antigens, HIV antigens, SIV antigens, and rotavirus antigens.

Working Examples and Guidance Provided

The breadth of the presently pending claims encompasses routes of administering DNA vaccines, including intravenous, intramuscular, intraperitoneal, intradermal and subcutaneous. The working examples of the instant application only demonstrate the use of (1) IV, IM, and gene gun (intradermal) combination vaccination for HIV antigens in mice, (2) gene gun (intradermal) for rotavirus antigens in mice, (3) IV, IP, SC, intratracheal, intrabursal, intraorbital for influenza antigens in fowl, (4) IV, IP, IM, intranasal, ID, SC routes for influenza antigens in mice, (5) IM for influenza antigens in ferrets (6) ID for influenza antigens in ferrets, (7) IV, IM, ID for SIV in monkeys. It appears the inventors have tested several routes of administration, and induced certain degree of protection, particularly for influenza. However the results for influenza cannot be extended to all types of infectious agents such as HIV, to achieve a clinically beneficial effect.

State of the Art and Analysis of the Issues

In view of the state of the art in the routes of genetic vaccination, *McCluskie et al* (Mol Med 1999 May;5:287-300) teach "ROUTES OF ADMINISTRATION OF PLASMID DNA VACCINES INFLUENCES THE STRENGTH AND NATURE OF IMMUNE RESPONSES IN MICE AND NON-HUMAN PRIMATES. HOWEVER, THE RESULTS IN MICE WERE NOT ALWAYS PREDICTIVE OF THOSE IN MONKEYS AND THIS IS LIKELY TRUE FOR HUMANS AS WELL. OPTIMAL DOSE AND IMMUNIZATION

SCHEDULE WILL MOST LIKELY VARY BETWEEN SPECIES. IT IS NOT CLEAR WHETHER RESULTS IN NON-HUMAN PRIMATES WILL BE PREDICTIVE OF RESULTS IN HUMANS, THUS ADDITIONAL STUDIES ARE REQUIRED." (See abstract). *Torres et al* (J Immunol 1997;158:4529-32) teach "TRANSFECTED CELLS IN GENE GUN-BOMBARDED SKIN, BUT NOT NEEDLE-INJECTED MUSCLE, PLAY A CENTRAL ROLE IN DNA-INITIATED AB AND CTL RESPONSE" (abstract). *Nakano et al* (J Virol 1997;71:7101-09) teach that immune reactivity with plasmid DNA encoding HCV-E2 antigenic domains is linked to the injection mode, "DIFFERENT ROUTES OF INJECTION OF HCV E2 PLASMID CAN RESULT IN QUANTITATIVELY AND QUALITATIVELY DIFFERENT HUMORAL IMMUNE RESPONSES" (see abstract).

Therefore additional and undue experimentation would be required by others in order to make and use the invention for all routes of administration, in particular for HIV.

ENABLEMENT for HIV and SIV DNA-Vaccines

Claims 1, 4, 5, 9-10, 16, 17, 24, 28-29, 32, 36, 40-41, 44-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of the Invention

The nature of the rejected claims of the invention are broadly drawn to administering to a vertebrate (further mammal and still further human), a vector encoding any protein from SIV or HIV, to elicit protective immunity.

Working Examples and Guidance Provided

The specification does not enable any person skilled in the art to make and use the invention commensurate in scope of these claims. Examples 12-14 describe mouse and Rhesus monkey experiments seeking to demonstrate cellular immune response to HIV and SIV DNA-vaccines, respectively. While these seem to be excellent pre-clinical studies that may support a proof-of-concept, they are insufficient to enable the invention as providing protective immunity against SIV and HIV, infection or disease progression. Further experimentation would be required by any skilled artisan before the invention of the instant application could be used for as a method of innumizing a mammal (or human) whereby the subject would be protected from disease.

State of the Art and Analysis of the Issues

At the time the application was filed, those skilled in the art recognized that it is impossible to predict whether an untested antigen of an infectious pathogen will elicit a protective immune response in a given type of animal, and that results observed in animal model systems following administration of a DNA expression vector cannot be

assumed to be predictive of outcome of efficacy in applications in other species of animal or in humans. With particular regard to HIV, Haynes et al. (Science.1993; 260:1279-1286) teach that the immune correlates for protection against HIV are not known, and that there is no animal model that mirrors human HIV infection, and that current animal models for SIV or HIV do not develop AIDS symptoms or anti-HIV immune responses analogous to those of HIV-infected humans, so that it is impossible to determine whether observation of a given immune response to an immunodeficiency virus vaccine in an animal model indicates that the tested vaccine actually confers protection against the virus in a human (page 1280, left column). In support of this view, the recent disclosure by Weiner et al. (see Weiss, Washington Post, p. A2, Apr. 30, 1997) that protective immunity against HIV could be elicited in chimpanzees by administering DNA encoding 4 different HIV genes was met with skepticism by those skilled in the art, who noted that "many other AIDS vaccines have looked similarly promising at the same early stage of development, only to fail in humans."

Given the breadth of the claims, which encompass vectors comprising any type of promoter and genes encoding any SIV or HIV protein, and given the unpredictability of the operation of the claimed invention and the lack of correlative examples as discussed above, one skilled in the art would reasonably have considered that at the time the application was filed, undue experimentation would have been required to use the claimed invention to successfully elicit protective immunity against SIV or HIV infection in a vertebrate, mammal or human.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 8, 14, 16, 17, 24, 27, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Dyall-Smith et al. (USPat-5,332,658).

Claims 1 and 16 are directed to methods of immunizing a vertebrate using a DNA transcription unit comprising DNA encoding a desired antigen operatively linked to a DNA promoter, which elicits a humoral and/or cell-mediated immune response against a desired antigen. Claim 4 is directed to the limitation that the method is capable of eliciting a protective immune response. Claims 5 and 24 are directed to the limitation that the infectious agent is a virus. Claims 8 and 27 are directed to the further limitation that the virus is a rotavirus. Claims 30-31 are directed to the limitations of delivery to a "human mammal."

Dyall-Smith et al. teach "human rotavirus gene encoding the major outer capsid glycoprotein (VP7) of the human rotavirus" (abstract). Dyall-Smith et al. further teach the "vaccine may comprise the isolated gene, or a portion or sub-unit thereof, in accordance with the present invention, inserted into a viral vector such as adenovirus or vaccinia." (column 3, lines 1-4). Dyall-Smith et al. teach rotavirus antigens that "elicit protective immunity." (column 1, line 39). It is inherent that protective immunity of a

vaccine would have produced a humoral and/or cell-mediated immune response. It is also inherent that the viral vector vaccine of Dyall-Smith et al. would have a promoter, in order to produce a rotavirus peptide and subsequent immune response. Dyall-Smith et al. intend to use their vaccine for humans, as described in their background material, "In many third world countries rotavirus infection causes significant infant mortality. The World Health Organization has recommended that a vaccine against human rotavirus be developed as soon as possible" (column 1, lines 21-25).

Claim 14 is directed to the further limitations of "physiological acceptable carrier" and "mucosal surface of the vertebrate". Claim 17 is directed to the further limitation of administration to "mucosal surface." Dyall-Smith et al. teach "viral vaccines may employ...viruses dispersed in a pharmaceutical diluent such as a liquid suitable for oral administration" (column 3, lines 5-7).

Accordingly, Dyall-Smith et al. anticipated claims 1, 4, 5, 8, 14, 16, 17, 24, 27, and 30-31.

Claims 1-6, 10-19, 21-25, 29-37, 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Eppstein et al. (USPat-5,049,386).

Claims 1 and 16 are directed to methods of immunizing a vertebrate using a DNA transcription unit comprising DNA encoding a desired antigen operatively linked to a DNA promoter, which elicits a humoral and/or cell-mediated immune response against a desired antigen. Eppstein et al. teach "vaccine administration...to an animal or mammal in need thereof" (column 15, lines 7-10) including "delivery of...DNA...plasmids

containing promoters" (column 10, lines 15-27) that enhance "humoral and/or cellular immunity, to an antigen of interest" (column 12, lines 41-42).

Claim 2 is directed to a promoter of nonretroviral origin. Eppstein et al. teach "SV40 early promoter" (column 56, line 48) which is from a DNA virus and therefore not a retroviral promoter.

Claim 3 is directed to a promoter of retroviral origin. Eppstein et al. teach "Rouse Sarcoma viral promoter" (column 56, line 49) which is a retroviral promoter.

Claim 4 is directed to the limitation that the method is capable of eliciting a protective immune response. Eppstein et al. teach "sufficient immunological response so as to impart protection to the subject from the subsequent exposure to the material or organism" (column 15, lines 18-20)

Claim 5 is directed to "infectious agent is a virus." Claim 6 is directed to the further limitation that the virus is influenza virus. Claim 10 is directed to the further limitation that the virus is HIV. Eppstein et al teach "antigens of...influenza viruses...or...human immunodeficiency viruses." (column 15, lines 46-49).

Claim 11 is directed to a vaccination of a "mammal." Eppstein et al. teach "vaccine administration...to an animal or mammal in need thereof" (column 15, lines 7-10).

Claim 12 is directed to the further limitation that the mammal is a human. Eppstein et al teach "therapeutic administration to a human" (column 8, lines 19-20).

Claim 13 is directed to physiologically acceptable carrier and to various routes of administration, including IV, IM, IP, ID, and Subcut. Eppstein et al. teach "conventional

pharmaceutical carrier or excipient" (column 12, lines 66-67) and vaccine administration methods "such as subcutaneous, intraperitoneal, intramuscular or intravenous or orally, or by intranasal administration" (column 15, lines 11-13). Since intranasal administration is a species of mucosal surface administration, Eppstein et al. also satisfies the limitation of claim 14.

Claim 15 is directed to the further limitation of a "microsphere-encapsulated DNA transcription unit." Eppstein et al teach "liposomes...microscopic vesicles...spheres" (column 1, lines 26-28) and further that the "liposomes have been used to introduce DNA into cells" (column 2, lines 55-56). Eppstein further teaches "antigen of interest...is incorporated in the lipid-containing vesicles" (column 12, lines 43)

Claim 17 is directed to the combined limitations of claims 1, 13-14, and the further limitation that the "vertebrate is protected from disease caused by an infectious agent." Eppstein et al teach "protection to the subject from the subsequent exposure to the material or organism" (column 15, lines).

Claim 18 is directed to a promoter of nonretroviral origin. Eppstein et al. teach "SV40 early promoter" (column 56, line 48) which is from a DNA virus and therefore not a retroviral promoter.

Claim 19 is directed to a promoter of retroviral origin. Eppstein et al. teach "Rouse Sarcoma viral promoter" (column 56, line 49) which is a retroviral promoter.

Claim 21 is directed to administration to the nasal mucosal surface. Eppstein et al. teach vaccine administration methods such as "intranasal administration" (column 15, line 13).

Claim 23 is directed to the further limitation of a "microsphere-encapsulated DNA transcription unit." Eppstein et al teach "liposomes…microscopic vesicles…spheres" (column 1, lines 26-28) and further that the "liposomes have been used to introduce DNA into cells" (column 2, lines 55-56). Eppstein further teaches "antigen of interest…is incorporated in the lipid-containing vesicles" (column 12, lines 43)

Claim 24 is directed to "infectious agent is a virus." Claim 25 is directed to the further limitation that the virus is influenza virus. Claim 29 is directed to the further limitation that the virus is HIV. Eppstein et al teach "antigens of…influenza viruses…or…human immunodeficiency viruses." (column 15, lines 46-49).

Claim 30 is directed to a vaccination of a "mammal." Eppstein et al. teach "vaccine administration…to an animal or mammal in need thereof" (column 15, lines 7-10).

Claim 31 is directed to the further limitation that the mammal is a human. Eppstein et al teach "therapeutic administration to a human" (column 8, lines 19-20).

Claim 32 is directed to "A method of immunizing a vertebrate against an infectious agent, said method comprising administering parenterally to the vertebrate a DNA transcription unit comprising DNA encoding a desired antigen of an infectious agent operatively linked to DNA which is a promoter region, in a physiologically acceptable carrier, thereby eliciting a humoral or cell-mediated immune response, or both, against a desired antigen, whereby the vertebrate is protected from disease caused by the infectious agent." Eppstein et al. teach "vaccine administration…to an animal or mammal in need thereof" (column 15, lines 7-10) including "delivery

of...DNA...plasmids containing promoters" (column 10, lines 15-27) that enhance "humoral and/or cellular immunity, to an antigen of interest" (column 12, lines 41-42). Eppstein et al. teach "conventional pharmaceutical carrier or excipient" (column 12, lines 66-67). Eppstein et al teach "parenteral administration" (column 13, line 33).

Claim 33 is directed to various routes of administration, including IV, IM, IP, ID, and Subcut. Eppstein et al. teach vaccine administration methods "such as subcutaneous, intraperitoneal, intramuscular or intravenous or orally, or by intranasal administration" (column 15, lines 11-13). Further, Eppstein et al. teach "transdermal" administration (column 4, line 19).

Claim 34 is directed to a promoter of nonretroviral origin. Eppstein et al. teach "SV40 early promoter" (column 56, line 48) which is from a DNA virus and therefore not a retroviral promoter.

Claim 35 is directed to a promoter of retroviral origin. Eppstein et al. teach "Rouse Sarcoma viral promoter" (column 56, line 49) which is a retroviral promoter.

Claim 36 is directed to "infectious agent is a virus." Claim 37 is directed to the further limitation that the virus is influenza virus. Claim 41 is directed to the further limitation that the virus is HIV. Eppstein et al teach "antigens of...influenza viruses...or...human immunodeficiency viruses." (column 15, lines 46-49).

Claim 42 is directed to a vaccination of a "mammal." Eppstein et al. teach "vaccine administration...to an animal or mammal in need thereof" (column 15, lines 7-10).

Claim 43 is directed to the further limitation that the mammal is a human.

Eppstein et al teach "therapeutic administration to a human" (column 8, lines 19-20).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-7, 11-13, 16, 32-34, 36-38, 42-43, and 52-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,643,578. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of USPat-5,643,578, are a species of the more broadly claimed genus encompassed by the instant application.

Claims 1 and 16 of the instant application are broadly drawn to methods of immunizing that elicit an immune response against a desired antigen. Claim 1 of the issued patent, USPat-5,643,578, teaches a method of immunization that protects a vertebrate from a disease caused by an infectious agent. A method of immunization that protects a vertebrate from a disease caused by an infectious agent would have elicited an immune response. The referenced patent states the "term 'immunizing' refers herein to the production of an immune response in a vertebrate which protects (partially or totally) from the manifestations of infection (i.e., disease) caused by an infectious agent." (column 2, lines 48-51).

Claim 2, 18 and 34 of the instant application are drawn to a nonretroviral promoter, while the specification of the referenced patent teaches CMV promoter, giving the meaning of a nonretroviral promoter to "promoter region" of claims 1, 8, 14, and 17 of the patent.

Claim 4 of the instant application is directed to eliciting a protective immune response against an infectious agent, which is nearly identical to claim 1 of the referenced patent.

Claims 5, 24 and 36 of the instant application are directed to the infectious agent is a virus. Claims 3 and 11 of the referenced patent teach the same limitation.

Claims 6, 25 and 37 of the instant application are directed to the further limitation of the infectious agent being influenza virus. Claims 14-15 and 17-18 of the referenced patent teach, in varying language, the protection against the infectious agent, influenza.

Claim 7 and 38 of the instant application are directed to a desire antigen that is influenza virus hemagglutinin. Claims 1, 15, and 18 of the referenced patent teach the same limitation.

Claims 10, 29 and 41 of the instant application are directed to HIV. Reading claim 1 in light of the specification of the referenced patent teaches HIV (column 3, lines 28-29).

Claims 11, 30 and 42 of the instant application are directed to the limitation that the subject of immunization is a mammal; claims 12, 31 and 43 further limit this mammal to a human. Claims 4-5 and 12-13 of the referenced patent teach the human mammal.

Claim 13 and 32-33 of the instant application are directed a physiologically acceptable carrier and various routes of administration. Claim 6 of the referenced patent teaches the same limitations.

Claim 14 and 17 of the instant application is directed to administration to the mucosal surface. Claim 7-8 and 17 of the referenced patent teach the same limitation.

Claim 21 of the instant application is directed to nasal mucosal surface. Claim 10 of the referenced patent teach the same limitation.

Claim 52 of the instant application is directed to method of immunizing against influenza. Claims 1, 8, 14 and 17 of the referenced patent teach the same method.

Claim 53 of the instant application is directed to a method of immunizing against influenza by administering two or more transcription units comprising different antigens. Claims 1, 8, 14 and 17 of the referenced patent teach a method of immunizing against

influenza by administering a DNA transcription unit comprising hemagglutinin or influenza virus antigens. In light of the specification of the referenced patent, a transcription unit may produce one or more antigens, "a DNA transcription unit which comprises DNA encoding a desired antigen or antigens." (column 1, lines 43-44). Accordingly, the referenced patent teaches the limitations of Claim 53 that more than one antigen of influenza is administered for vaccination.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Art Unit 1633

Q. JANICE LI, M.D.
PRIMARY EXAMINER

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER